

PSJ9 Exh 35

Standard Operating Procedures (SOP)
809-V HDS SOP CSOMP Divisional Policy



Approved By: Thomas J. Twitty	Date: 05/07/2008	Implementation Date: 05/07/2008
Revision By:	Date:	Implementation Date:

Policy Identification

809-V HDS SOP Controlled Substance Order Monitoring Program (CSOMP)
Divisional Policy

Revision

Original

Policy Statement

It is the policy of H. D. Smith to comply with the requirements of 21 C.F.R. 1301.74(b) to design and operate a system to disclose to the registrant suspicious orders of controlled substances. With special provisions through DEA headquarters, H. D. Smith shall report suspicious orders, when discovered, to DEA headquarters.

The purpose of this document is to describe the Divisional standard operating procedures for identifying, releasing or upholding, and notating customer controlled substance orders that have been suspended by CSOMP.

This policy applies to all H. D. Smith associates, and the Designated Representative shall be responsible for the enforcements of all policies. Associates violating this policy are subject to discipline up to and including termination of employment.

Any exceptions to this policy shall be reported in writing to the Designated Representative. The Designated Representative shall then report any exceptions in writing to the Vice President Division Manager (VPDM), and to the Vice President of Operations. The Designated Representative shall document all exceptions and actions taken.

Definitions

21 C.F.R. 1301.74(b): The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of

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suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Procedure

Suspended Order Editing

1. Securing Authority:

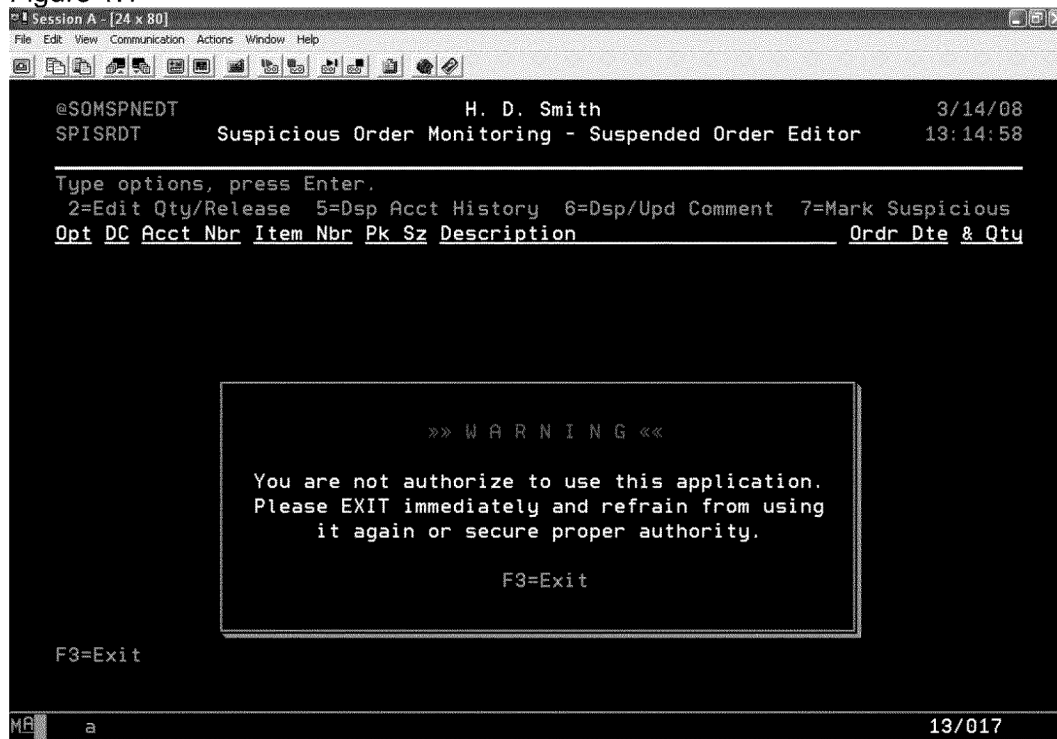
The Director of Corporate Compliance and Security shall have the authority to grant access to the CSOMP. Divisional authority shall be granted for the purpose of identifying suspended orders, releasing suspended orders, upholding the suspended status and notating the suspended records.

For authorized users to gain access to the CSOMP on the AS 400, perform the following tasks:

- a) Log on to the AS/400.
- b) On the menu line, enter GO SOMMENU
- c) Enter the number corresponding to the division.
- d) The Suspended Order Editor will be displayed.

Figure 1.1 The system will display a warning, and access to the CSOMP will not be allowed for unauthorized users.

Figure 1.1



2. Display Suspended Order:

At this point, all suspended orders will be displayed for the user to identify, as shown in Figure 2.1.

Figure 2.1

Session A: [24 x 80]
File Edit View Communication Actions Window Help

@SOMSPNEDT H. D. Smith 3/17/08
SPISRDT Suspicious Order Monitoring - Suspended Order Editor 15:03:19

Type options, press Enter. Position to Acct Nbr: 0
2=Edit Qty/Release 5=Dsp Acct History 6=Dsp/Upd Comment

Opt	DC	Acct Nbr	Item Nbr	Pk Sz	Description	Ordr Dte & Qty
01	10103112	109-1834	10		MIDAZOLAM 1MG/ML 5ML P/F BED	03/11/08 3
01	10103112	022-0251	25		FENTANYL 5ML FTV H0S09425	03/11/08 3
01	10103112	107-9821	25		FENTANYL 2ML FTV H0S09422	03/11/08 2
01	10103113	191-0124	100		METADATE CD 20MG 53014058007	03/11/08 1
01	10103113	132-6636	100		ADDERALL XR 15MG 54092038501	03/11/08 1
01	10103113	132-6644	100		ADDERALL XR 25MG 54092038901	03/11/08 1
01	10103113	143-0149	100		DEXTROAMP SACC TB 10MG RB 0901	03/11/08 3
01	10103113	143-0164	100		DEXTROAMP SACC TB 20MG RB 1001	03/11/08 2
01	10103113	143-0230	100		DEXTROAMP SACC TB 5MG RB 0801	03/11/08 3
01	10103114	114-2215			HYDROCOD/APAP ELIX PT PA 65516	03/11/08 4
01	10103114	150-7490			OXYCODONE SOL 20MG 30ML MA 830	03/11/08 6
01	10103114	019-0181	100		OXYCODONE TABS 5MG MA 055201	03/11/08 6
01	10103114	107-7874	500		OXYCOD/APAP TAB 5/325 MA 1205	03/11/08 1
01	10103114	169-9693	100		OXYCOD/APAP TAB 10/325 MA 2301	03/11/08 4
01	10103114	121-0103	100		PROPOX NAP 50 TAB ORG QT 6521	03/11/08 2

More...

F3=Exit F11=Fold/Drop

MA a A 07/003

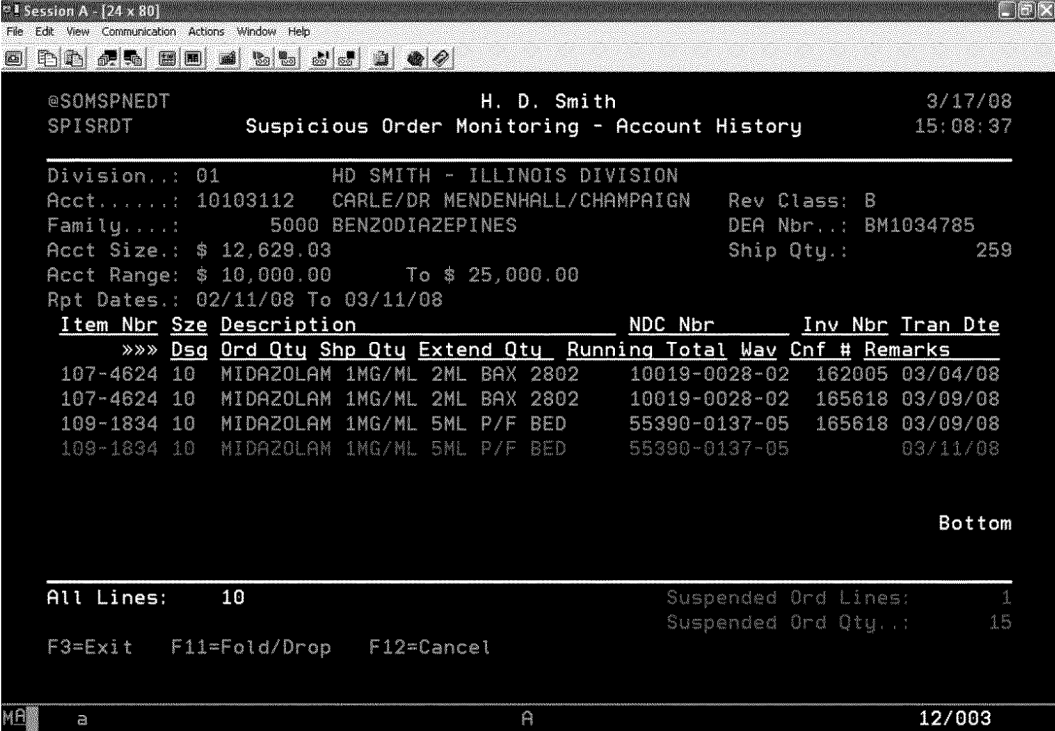
Additional information can be shown or hidden by pressing function key F11 to drop/fold as shown in Figure 2.2, 2.4, 2.5 and 2.6.

Figure 2.2



Account history can be displayed by typing option 5 one line at a time, see Figure 2.3.

Figure 2.3



As you will notice, each line will be differentiated by means of color coding.

- **Blue:** shipped order(s) under given URL,
- **Yellow:** shipped order(s) over given URL
- **Red:** suspended order(s).

Figure 2.4

Session A - [24 x 80]

File
Edit
View
Communication
Actions
Window
Help

@SOMSPNEDT

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3/17/08

SPISRDT

Suspicious Order Monitoring - Account History

15:08:37

Division..: 01

HD SMITH - ILLINOIS DIVISION

Acct.....: 10103112

CARLE/DR MENDENHALL/CHAMPAIGN

Rev Class: B

Family....: 5000

BENZODIAZEPINES

DEA Nbr..: BM1034785

Acct Size: \$ 12,629.03

Ship Qty.: 259

Acct Range: \$ 10,000.00

To \$ 25,000.00

Rpt Dates.: 02/11/08 To 03/11/08

Item	Nbr	Size	Description	NDC Nbr	Inv Nbr	Tran Dte
>>>>	Dsg	Ord Qty	Shp Qty	Extend Qty	Running Total	Wav
107-4624	10	MIDAZOLAM	1MG/ML	2ML BAX	2802	10019-0028-02
						162005 03/04/08
>>>>	VI	10	10	20		227
107-4624	10	MIDAZOLAM	1MG/ML	2ML BAX	2802	10019-0028-02
						165618 03/09/08
>>>>	VI	6	6	12		239
109-1834	10	MIDAZOLAM	1MG/ML	5ML P/F	BED	55390-0137-05
						165618 03/09/08
>>>>	VI	4	4	20		259

More...

All Lines: 10

Suspended Ord Lines: 1

Suspended Ord Qty.: 15

F3=Exit

F11=Fold/Drop

F12=Cancel

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Figure 2.5

Session A - [24 x 80]

File Edit View Communication Actions Window Help

@SOMSPNEDT H. D. Smith 3/17/08
SPISRDT Suspicious Order Monitoring - Account History 15:08:37

Division..: 01 HD SMITH - ILLINOIS DIVISION
Acct.....: 10103112 CARLE/DR MENDENHALL/CHAMPAIGN Rev Class: B
Family....: 5000 BENZODIAZEPINES DEA Nbr...: BM1034785
Acct Size.: \$ 12,629.03 Ship Qty.: 259
Acct Range: \$ 10,000.00 To \$ 25,000.00
Rpt Dates.: 02/11/08 To 03/11/08

Item Nbr	Size	Description	NDC Nbr	Inv Nbr	Tran Dte
>>>	Dsg	Ord Qty Shp Qty Extend Qty	Running Total	Wav	Cnf # Remarks
109-1834	10	MIDAZOLAM 1MG/ML 5ML P/F BED	55390-0137-05		03/11/08
>>>	VI	3 0 15	36	47260	

Bottom

All Lines: 10 Suspended Ord Lines: 1
Suspended Ord Qty.: 15

F3=Exit F11=Fold/Drop F12=Cancel

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Figure 2.6

Session A - [24 x 80]

File Edit View Communication Actions Window Help

@SOMSPNEDT H. D. Smith 3/17/08
SPISRDT Suspicious Order Monitoring - Account History 15:14:36

Division..: 01 HD SMITH - ILLINOIS DIVISION
Acct.....: 10103113 CARLE/DR MENDENHALL/CHAMPAIGN Rev Class: G
Family....: 2000 AMPHETAMINE DEA Nbr...: BM1034785
Acct Size.: \$ 12,629.03 Ship Qty.: 0
Acct Range: \$ 10,000.00 To \$ 25,000.00
Rpt Dates.: 02/11/08 To 03/11/08

Item Nbr	Size	Description	NDC Nbr	Inv Nbr	Tran Dte
>>>	Dsg	Ord Qty Shp Qty Extend Qty	Running Total	Wav	Cnf # Remarks
132-6636	100	ADDERALL XR 15MG	54092038501	54092-0385-01	03/11/08
132-6644	100	ADDERALL XR 25MG	54092038901	54092-0389-01	03/11/08
132-6628	100	ADDERALL XR 5MG	54092038101	54092-0381-01	03/11/08
143-0230	100	DEXTROAMP SACC TB 5MG RB 0801	63304-0908-01		03/11/08
143-0149	100	DEXTROAMP SACC TB 10MG RB 0901	63304-0909-01		03/11/08
143-0164	100	DEXTROAMP SACC TB 20MG RB 1001	63304-0910-01		03/11/08

Bottom

All Lines: 6 Suspended Ord Lines: 6
Suspended Ord Qty.: 1100

F3=Exit F11=Fold/Drop F12=Cancel

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At the footer, you can also see legends corresponding to how many lines for each color category. If a suspended order has been 'Released' or 'Marked as Suspicious' – on the 'Remarks' column it will appear 'Released' or 'Suspicious' respectively as shown in Figure 2.6. To go back to previous screen press function key F12, or to exit, press function key F3.

3. Release Suspended Order with Optional Quantity Change:

An authorized user will have the ability to release a suspended order in its entirety, or the user may enter a different quantity to release. Any order released by the division will be done under strict guidelines. Orders may be released based on the following criteria:

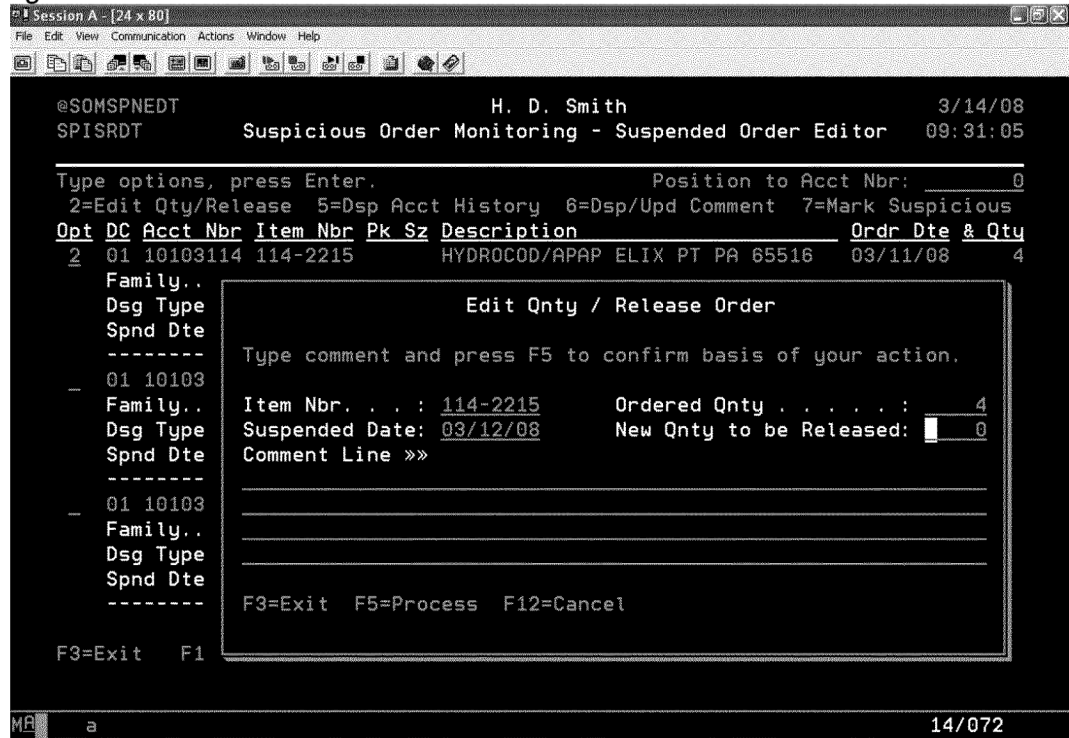
- a) Division is able to contact customer, and customer acknowledges that there has been a mistake in ordering. The new quantity may be entered and released.
- b) There is an obvious mistake in ordering, such as a "fat fingered" order. Based on account history, a new quantity may be entered and released.
- c) A new account order (initial 90 days) is suspended due to lack of account history. This order may be released in its entirety.
- d) A hospital account has been suspended. This may be released and will be reviewed the next day.

The division shall not release any order or portion of the order for any other reason than stated above, without permission of the Director of Corporate Compliance and Security.

To release all or a portion of an order, user must type option 2 from the Suspended Order Editor screen. See Figure 3.1. If the entire order is to be released, then nothing needs to be entered into the New Quantity to be Released field. If a new quantity is to be released, then the user needs to enter that amount in the New Quantity to be Released field. Entering a reason for the order release in the Comment Line is necessary for this action. Enter F5 to process the release.

Once an order has been released, it will be sent back to the Order File and the next Wave will process it for picking as if it wasn't suspended.

Figure 3.1.



4. Display or Update Comment:

At any point in time, an authorized user may display or update comments to track the status of a suspended order. In doing so, the user must type in option 6 and the comment will be shown and can be updated. See Figure 4.1.

Figure 4.1.

Session A - [24 x 80]

File Edit View Communication Actions Window Help

@SOMSPNEDT H. D. Smith 3/14/08
SPISRDT Suspicious Order Monitoring - Suspended Order Editor 09:37:41

Type options, press Enter. Position to Acct Nbr: 0

2=Edit Qty/Release 5=Dsp Acct History 6=Dsp/Upd Comment 7=Mark Suspicious

Opt	DC	Acct Nbr	Item Nbr	Pk Sz	Description	Ordr Dte	Qty
6	01	10103114	114-2215		HYDROCOD/APAP ELIX PT PA 65516	03/11/08	4

Family..
Dsg Type
Spnd Dte

01 10103
Family..
Dsg Type
Spnd Dte

01 10103
Family..
Dsg Type
Spnd Dte

Display / Update Comments

Type comment and press F5 to confirm basis of your action.

Item Nbr. . . : 114-2215 Ordered Qty : 4

Suspended Date: 03/12/08

Comment Line >>

F3=Exit F5=Process F12=Cancel

F3=Exit F1

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Training

The Designated Representative or designee shall be responsible for training divisional associates on all relevant policies and procedures.

Training shall be conducted on this policy at time of hire and anytime that revisions are made. Training may be conducted throughout the year, as needed.

Training shall be conducted in a classroom setting, and all warehouse associates shall complete a written training document certifying that they have read and fully understand the herein procedure.

All associate training shall be documented and maintained in the associate's personnel file.

Review Schedule

The Vice President of Operations will review each policy and procedure annually for relevance and applicability.

References

21 CFR Parts 1300 to end